DETAILED ACTION

1. Applicant's amendment filed 13 November 2009 has been entered and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 11, 12, 21-23, 26 and 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide sufficient support for the new limitation of amended claim 11, wherein the terminal comprising "conductors layered along the at least one external surface of the circuit substrate". It is noted that the specification teaches a terminal, but does not teach the terminal comprising conductors layered along the at least one external surface of the circuit substrate. Therefore the specification does not provide sufficient support for the amended claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 11, 12, 21-23, 26, 39-41, 43, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2002/0004246) in view of Crosby (US 6,217,744) further in view of Mills et al. (US 2003/0201176) and Holmes, II et al. (US 5,371,687).

Daniels et al. teach a test system comprising:

a test strip having:

a test stripe (anti-analyte 1 epitope B, Fig. 1; par. 218),

a control stripe (control line, Fig. 1; par. 218), and

a receiving zone (area under arrow pointing to test strip under sample is sample receiving zone, Fig. 1; sample pad, par. 219),

the test strip being capable of generating a response at the test strip and the control stripe subsequent to contact of a single liquid sample in the receiving zone (par. 219 and 220; one liquid sample is applied to the test strip, sample is either mixed with detection reagent prior to application to test strip and sample and detection reagent are applied together or detection reagent is embedded in

the test strip and only the single liquid sample is applied to the test strip, par. 217-219), the test stripe containing a labeling substance that comprises first persistent fluorescent structures that emits light having a first frequency and second persistent fluorescent structures that emit light having a second frequency, wherein each of the first persistent fluorescent structures is attached to a substance that is capable of binding the first structure to a target analyte after a sample fluid containing the target analyte is applied to the receiving zone (each detection reagent is associated with a nanocrystal having a distinct emission peak and nanocrystal is a persistent fluorescent structure, par. 207; capture and control reagents bind the first and second structures and are present in a chromatographic medium therefore the first and second nanocrystal structures are present in a medium, par. 201; emission peak of nanocrystal incorporated into control is distinct from that exhibited by nanocrystals of the first detection reagent therefore first and second nanocrystals emit at different frequencies, par. 198);

a light source positioned to illuminate a target area and a control area on the medium within the single use module, the target area encompassing the test stripe and the control area encompassing the control stripe (par. 213);

a first photodetector positioned to measure light of the first frequency from the target area (multiple detectors for each light emission frequency, par. 214); and

a second photodetector positioned to measure light of the second frequency from the control area, wherein a signal from the second photodetector indicating an intensity

above a threshold level indicates that the sample has passed through the target area (separate detector for each detection region with a different emission frequency, par. 214; control region has a different emission frequency than detection region, par. 198; detection of nanocrystals in the control region occurs in the presence or absence of analyte and therefore indicates that the sample has passed through the medium, par. 242).

Daniels et al. fail to teach the first and second photodetectors and medium contained in a single-use module, a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of the housing of the single use module for receiving electrical power from a source external to the single-use module, wherein the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the circuit substrate.

Crosby teaches a photodetector and medium necessary for optical detection contained in a single use module (optical components and porous membrane are part of the disposable device, optical components comprise the photodetector, col. 5, lines 64-col. 6, line 13) and inserted into a reusable module for communication of test signals between the single-use module and reusable module (communication between disposable analysis device and information gather and storage system, disposable device is single use and information gathering system is reusable, col. 6, lines 57-67; col. 7, lines 37-45) and the single use module comprising an external terminal receiving electrical power for the electronics in the device, including light sources and

photodetectors (capacitor is external terminal that receives electrical power, col. 8, lines 28-40; electronics include light source and photodetectors, col. 6, lines 46-50), wherein the reusable module has a receptacle into which the external terminal of the single use module can be inserted to provide electrical power and communicates test signals between single use module and reusable module (device is brought in proximity to console, col. 8, lines 28-40; device may alternatively be placed into the console for transfer of data and to provide electrical power, col. 7, lines 6-10), in order to provide a self powered device that resists corrosion and degradation. Crosby teaches that while not preferable, it is possible to directly electrically connect the device to a reader for power supply and information gathering (col. 6, lines 57-67) and Crosby also teaches that power to the diagnostic device may be provided inductively, but not conductively, by an electrical power source external to the single-use module (col. 8, lines 28-40). All disclosures of non-preferred embodiments must be considered. *In re Nehrenberg*, 126 PQ 383. *In re Boe*, 148 PQ 507. *In re Mill and Palmer*, 176 USPQ 196 (CCPA 1972). *In re Simon*, 174 PQ 114. *In re Lamberti et al.*, 192 PQ 278 (CCPA 1976).

Mills et al. teach a test strip having a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the module (plug end inserts into a meter, par. 40, electrodes are part of a circuit that extend past the housing and connects the module to the meter, par. 9) for receiving electrical power from a source external to the module (par. 57) and for communicating information to a reusable module (meter) (measurements taken by meter, therefore information from the test strip is communicated to the meter which is

the reusable module, par. 79), the terminal comprising conductors layered along the at least one external surface of the circuit substrate (333, 334, 335, 336 are the layered conductors, par. 99-103), in order to provide determination of various analyte concentrations using a sensor that is designed to facilitate production is large quantities using reliable and cost effective manufacturing methods.

Holmes, II et al. teach a module that has a terminal for insertion of a single use module (housing mated to data processing module, col. 3, lines 6-10), that has a terminal located on an external surface of the single-use module for conductively receiving electrical power from a source external to the single-use module and configured to be pluggably inserted into the receptacle of the reusable module for communicating test result signals (housing is mated to data processing module and conductors connect the module to an external power supply, col. 3, lines 19-36) and sample measurements over an extended period of time longer than the battery life of a device, in order to provide glucose measurements in a device that can interface with a printer, store larger numbers of patient glucose numbers, perform various calculations and interface a number of different types of glucose measurements to a computer.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the test system of Daniels et al., the photodetectors and medium necessary for optical detection contained in a single use module that can be inserted into a reusable module for communication of test signals as taught by Crosby, in order to provide small, point of care diagnostic tests that are small in size and produces a fast quantitative or qualitative result with increased reliability.

Although Crosby does not specifically teach two photodetectors, it would have been obvious to include all photodetectors of Daniels et al. necessary for detection in the single use device taught by Crosby. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Daniels et al. in view of Crosby, a terminal arranged along an external surface of a circuit substrate that extends through and beyond an external surface of a housing of a single-use module for conductively receiving electrical power from a source and for communicating information to a reusable module when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the externals surface of the circuit substrate as taught by Mills et al., in order to provide sample measurements over an extended period of time longer than the battery life of a device as taught by Holmes, II et al.

Although Mills et al. do not specifically teach the module having a terminal being single use, such a limitation is drawn to intended use of the module and claim 11 does not recite any specific structural limitations that render the module single-use. The module of Mills et al. contains the structural limitations for a single use module as recited in claim 11, which is the module having a terminal on the external surface of a circuit substrate that extends through and beyond an external surface of a circuit substrate of a housing of the single use module for receiving electrical power from a source external to the module and for communicating information to a reusable module (meter), when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the external surface of the circuit

substrate. Therefore the module taught by Mills et al. is capable of being disposed after a single use and reads on the instantly claimed single use module.

Daniels et al. in view of Crosby et al. further in view of Holmes, II et al. do not specifically teach the application of the single liquid sample to the receiving zone of the test strip excluding the use of the light source, the first photodetector and the second photodetector disposed within the single use module from being used to analyze an additional liquid sample different from the single liquid sample. However, such a limitation is drawn to intended use of the test strip and does not provide any specific structural limitations to the test strip and therefore the prior art must only be capable of performing the intended use. Since the combination of prior art references teach the required structural limitations of claim 1, the prior art is capable of performing the recited intended use. Furthermore, since Daniels et al. teach detection of multiple analyte in a *single* sample, it is clear the application of liquid to the test strip of Daniels et al. in a single housing as taught by Crosby et al. excludes the use of the test strip and the light source and first and second photodetectors with additional liquid samples.

With respect to claims 12, 21 and 22, Daniels et al. fail to teach a reusable module with a user interface indicating an electrical test result.

Crosby teaches the reusable module implementing a user interface capable of indicating a test result on a display (console is the information gathering and storage system and has a display screen to display results from the disposable device, col. 7, lines 37-50) and the test signals are electrical signals (col. 7, lines 14-25).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the test system of Daniels et al., a user interface that displays electrical test signals on a display as taught by Crosby, in order to provide small, point of care diagnostic tests that are small in size and produces a fast quantitative or qualitative result with increased reliability.

With respect to claim 23, Daniels et al. teach the first and second persistent fluorescent structures comprising quantum dots (par. 198 and 79).

Regarding claim 26, Daniels et al. teach the medium comprising a lateral-flow strip for performing a binding assay (par. 200-201) and the target area containing an immobilized substance that binds to and holds the complex including one of the first persistent structures and the target analyte (par. 200-201; capture reagent binds to the detection complex, par. 189; detection complex comprises analyte and nanocrystal, par. 137-139; capture reagent is in a capture region, par. 115).

With respect to claims 39 and 40, Daniels et al. teach the second persistent structures bind to the control strip (control ligands are in a control region, par. 115; control ligands bind to second persistent structures that have an emission frequency different from that in the capture region, par. 198). Daniels et al. also teach a first and second color filter corresponding to the first and second photodetector that transmit the first and second frequencies, respectively (multiple detectors are present, one for each region, and each has a bandpass filter for detecting a narrow wavelength range corresponding to the nanocrystal emission wavelength in the capture and control regions, par. 214).

With respect to claim 41, Daniels et al. teach the control stripe containing an immobilized substance that binds and retains the labeling substance (par. 26 and 38).

Regarding claims 43 and 45, Daniels et al. teach the optical system comprising a chromatic prism (prism spectrally resolves colors, par. 172) or diffractive grating (par. 171 and 172).

2. Claims 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2002/0004246) in view of Crosby (US 6,217,744) further in view of Mills et al. (US 2003/0201176) and Holmes, II et al. (US 5,371,687), as applied to claim 11, further in view of Cliche et al. (US 2003/0174743).

Daniels et al. in view of Crosby further in view of Mills et al. and Holmes, II et al. teach an optical system comprising a diffractive grating between the light source and the photodetectors (par. 171), but fail to teach an optical system comprising a thin-film filter.

Cliche et al. teach either a diffractive grating, thin-film filter (par. 69) or lenses (par. 89), in order to filter large optical bandwidths.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the system of Daniels et al. in view of Crosby further in view of Mills et al. and Holmes, II et al., an optical system comprising a thin-film filter as taught by Cliche et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent optical modification technique and since the same light signal would have been obtained. The use of alternative and functionally equivalent techniques would have

been desirable to those of ordinary skill in the art based on the economics and availability of components.

Response to Arguments

3. Applicant's arguments with respect to claims 11, 12, 21-23, 26 and 39-46 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the new limitation of a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a house of a single use module, wherein the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the circuit substrate.

Conclusion

4. No claims are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Primary Examiner, Art Unit 1641